

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Pursuant to the authority of Iowa Code chapter 136C and 2017 Iowa Acts, Senate File 250, the Iowa Department of Public Health hereby amends Chapter 41, “Safety Requirements for the Use of Radiation Machines and Certain Uses of Radioactive Materials,” Iowa Administrative Code.

These amendments incorporate the language from 2017 Iowa Acts, Senate File 250, into administrative rule to meet the intent of the legislation enacted during the 2017 Legislative Session to require communication of breast density composition as reflected on the patient’s mammogram to physicians and patients. The Department currently regulates the content of the mammography reports sent to the patient’s physicians and of the lay letters sent directly to the patients. These amendments add requirements concerning the content of these reports and letters to include language and educational references regarding the patient’s breast density and resulting risk of cancer incidence and impacts on mammography interpretation related to increased tissue density.

Notice of Intended Action was published in the Iowa Administrative Bulletin as **ARC 3210C** on July 19, 2017. No public comments were received. These amendments are identical to those published under Notice of Intended Action.

The State Board of Health adopted these amendments on September 13, 2017.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code chapter 136C and 2017 Iowa Acts, Senate File 250.

These amendments will become effective November 15, 2017.

The following amendments are adopted.

ITEM 1. Adopt the following new subparagraph **41.6(4)“b”(10)**:

(10) Information on a patient’s breast density, as categorized by an interpreting physician at the facility based on standards as defined in nationally recognized guidelines or systems for breast imaging reporting of mammography screening, including the breast imaging reporting and data system of the American College of Radiology.

ITEM 2. Adopt the following new subparagraph **41.6(4)“d”(3)**:

(3) The breast density information as designated in the report pursuant to 41.6(4)“b”(10) shall be included in the patient lay letter with a reference to a department-accepted site or document where the patient can obtain more information about breast density. For patients categorized as having heterogeneously dense breasts or extremely dense breasts, or an equivalent determination by another nationally recognized density gradient system, the notification to the patient shall include evidence-based information on dense breast tissue, the increased risk associated with dense breast tissue, and the effects of dense breast tissue on screening mammography and shall be stated in language appropriate for the facility’s patient population.

[Filed 9/14/17, effective 11/15/17]

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EDITOR’S NOTE: For replacement pages for IAC, see IAC Supplement 10/11/17.